

Alertas RAPEX mascarillas
Referencia: SOFM/MJA/apf
Fecha: 15/03/2021

ALERTAS EUROPEAS SOBRE MASCARILLAS QUE PRESENTAN RIESGOS PARA LA SALUD DE LOS USUARIOS

RAPEX es un sistema unificado de alerta e intercambio de información de productos peligrosos para la salud de los consumidores de la Unión Europea. Algunos de los productos notificados puede que no se encuentren disponibles en nuestro país, salvo que se adquieran a través de comercio electrónico.

Se adjuntan las últimas alertas RAPEX referentes a mascarillas de filtración para protección frente al contagio por COVID19. Las citas alertas son A11/00016/21, A12/00288/21, INFO-00054/21, INFO-00055/21, INFO-00056/21 y la INFO-00060/21

Estas alertas han sido incluidas en RAPEX por un Estado Miembro en cada caso. Las alertas calificadas como INFO, todas en esta ocasión, presentan un incumplimiento documental sin haberse realizado ensayos analíticos acerca de la seguridad del producto. La alerta A11/00016/21 ha sido categorizada como de riesgo no grave por la autoridad notificante.

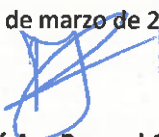
Le solicitamos que consulten frecuentemente las alertas emitidas por las autoridades europeas sobre mascarillas en el siguiente enlace, porque existen muchas en vigor en la actualidad y se incorporan continuamente.

https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&lng=es

Para cualquier duda puede dirigirse al Servicio de Ordenación Farmacéutica y Medicamentos:

- Tfno: 941 299 923
- mail: alertas.productossanitarios@larioja.org
- Carta: Servicio de Ordenación Farmacéutica y Medicamentos - Productos Sanitarios C/ Obispo Lepe s/n 26071 Logroño

Logroño, 15 de marzo de 2021



**Gobierno
de La Rioja**
Salud y Portavocía del Gobierno
Humanización, Prestaciones
y Farmacia

Dra. Mª José Aza Pascual-Salcedo
JEFA DE SERVICIO DE ORDENACIÓN
FARMACÉUTICA Y MEDICAMENTOS

Gobierno de La Rioja
Oficina Auxiliar de Registro
Salud

Fecha: 15 MAR. 2021

Hora:
Número: 52179



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
DISPOSABLE FACE MASKS

Brand (on the product or the packaging)
• **ELMED**

OECD Portal category (if known)
51000000 - Healthcare

Is the product (also) sold online?
No

Professional product?
No

Product description
Non-medical disposable protective mask, 3 layers of protection.

Packaging description
The product is sold in a white, blue and red cardboard box containing 50 pieces wrapped in a transparent plastic bag. The cardboard box is CE marked.

Product Recall

Type/number of model
• **TP-MSK-013 (Non Sterile)**

Batch number
• **TMSK013-2033**

Bar code
• **8681371811345**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A11/00016/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking but is not certified as protective equipment by a relevant body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures. Also, the labeling is confusing because on the cardboard box the mask is declared a "non-medical" one, while in the same time is mentioned the standard EN 14683: 2019.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
The product does not comply with the Personal Protective Equipment Regulation and with the relevant European standard EN 149.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Importer

**Ban on the marketing of the product and any accompanying measures
27/10/2020**

Year

Country of origin

Alert submitted by



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Starkit (auf der Verpackung), bd BADO (auf der Maske)

Brand (on the product or the packaging)
• **bd BADO**

OECD Portal category (if known)
85000000 - Safety / Protection - DIY

Is the product (also) sold online?
Unknown - unknown

Professional product?
No

Product description
Respiratory face-masks, claiming to pertain to categories N95, KN95, and FFP2.

Packaging description
The product is packed in a plastic foil and sold in sets of 4 in a black cardboard box (w x l x d = 15 cm x 16 cm x 2.3 cm).

Product Recall

Type/number of model

- **Art. Nr. Mask N98-4**
- **STKM-N9W01**

Batch number

- **MK472890002**

Bar code

- **4260299695776**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00288/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The particle/filter retention of the material is insufficient (measured values: as low as to 41 %) Consequently, an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection if not combined with additional protective measures.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
The product does not comply with the Personal Protective Equipment Regulation and with the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Compulsory measures

Other

Withdrawal of the product from the market 01/02/2021

Year

Country of origin

Alert submitted by



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Disposable daily protective mask for children

Brand (on the product or the packaging)
• **MAIKEN**

OECD Portal category (if known)
85000000 - Safety / Protection - DIY

Is the product (also) sold online?
No

Professional product?
No

Product description
Non-medical 3 layers disposable protective mask for children over 3 years old. The product is white with small drawings, and of size 145mm x 95mm.

Packaging description
The product is sold in a blue cardboard box containing 50 pieces.

Product Recall

Type/number of model
• **4**

• **Size: 145mm x 95mm**

Batch number
• **20200720**

Bar code
• **3874000016746**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00054/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product advertises a protective potential against (viral) particles but its filtering capacity has not been certified by the relevant (European) body.

Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional protective measures.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
The product does not comply with the Regulation on personal protective equipment and with the relevant European standard EN 149.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Retailer

Withdrawal of the product from the market 15/02/2021

Year

Country of origin

Alert submitted by



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Disposable Face Mask with Earloops

Brand (on the product or the packaging)
• **OUKE**

OECD Portal category (if known)
85000000 - Safety / Protection - DIY

Is the product (also) sold online?
No

Professional product?
No

Product description
Non-medical 3 layers disposable protective mask. The product indicates a size of 175mm x 95mm.

Packaging description
The product is sold in a white cardboard box containing 50 pieces.

Product Recall

Type/number of model
• **Size: 175mm x 95mm**

Batch number
Unknown

Bar code
• **6426485336405**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00055/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product advertises a protective potential against (viral) particles but its filtering capacity has not been certified by the relevant (European) body.

Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional protective measures.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
The product does not comply with the Regulation on personal protective equipment and with the relevant European standard EN 149.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Retailer

Withdrawal of the product from the market
15/02/2021

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Romania



Case number
INFO/00056/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product advertises a protective potential against (viral) particles but its filtering capacity has not been certified by the relevant (European) body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional protective measures.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
The product does not comply with the Personal Protective Equipment Regulation and with the relevant European standard EN 149.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Importer

**Import rejected at border
24/02/2021**

Product (what the product is)
Particle filter mask

Product Recall

Type/number of model
• HRM-06

Name (on the product or the packaging)
Disposable Protective Mask (Non-Medical Use)

Batch number
Unknown

Bar code
Unknown

Brand (on the product or the packaging)
• Hongren

Is the product counterfeit?
Unknown

OECD Portal category (if known)
85000000 - Safety / Protection - DIY

Is this notification linked to a Business Gateway case?

Is the product (also) sold online?
Unknown - no information available

Professional product?
No

Product description
Disposable face mask.

Packaging description
White and green cardboard box which contain 50 pcs. of product.

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Poland



Case number
INFO/00060/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product advertises a protective potential against particles but its filtering capacity has not been tested by a relevant competent European conformity assessment body. Consequently, it is not proven that the product fulfils the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
The product does not comply with Personal Protective Equipment Regulation

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Voluntary measures

Retailer

Stop of sales
25/01/2021

Product (what the product is)
Particle filter mask

Product Recall

Type/number of model
• 7100

Name (on the product or the packaging)
Hygienic disposable mask KN95

Batch number
Unknown

Brand (on the product or the packaging)
• Shield

Bar code
• 4772013226307

OECD Portal category (if known)
85000000 - Safety / Protection - DIY

Is the product counterfeited?
Unknown

Is this notification linked to a Business Gateway case?

Is the product (also) sold online?
No

Professional product?
No

Product description
White respiratory protective half-face mask of category KN95

Packaging description
White box with green elements, 100 masks inside

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Estonia